



Docket No. 41426-D/JPW/MS

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THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Ron S. Israeli, et al.
U.S. Serial No.: 08/470,735 Examiner: A. Caputo
Filed : June 6, 1995 Group Art Unit: 1806
For : PROSTATE-SPECIFIC MEMBRANE ANTIGEN AND USES
THEREOF

1185 Avenue of the Americas
New York, New York 10036
July 11, 1997

Assistant Commissioner for Patents
Washington, D.C. 20231

AUG 1 1997

Sir:

INFORMATION DISCLOSURE STATEMENT

In compliance with their duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following references, which are listed on the accompanying Form PTO-1449 attached hereto as Exhibit A, copies of which are attached hereto as Exhibits 1-42, respectively.

1. Hopp, T.P., U.S. Patent Number 4,554,101, issued November 19, 1985 (Exhibit 1);
2. Horoszewicz, J.S., U.S. Patent Number 5,162,504, issued November 10, 1992 (Exhibit 2);
3. Israeli, et al. , U.S. Patent Number 5,538,866, issued July 23, 1996 (Exhibit 3);
4. PCT International Publication Number WO 94/09820, International Publication Date May 11, 1994 (Exhibit 4);

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5. Abdel-Nabi, H., et al. (1992) "Monoclonal Antibodies and Radioimmunoconjugates in the Diagnosis and Treatment of Prostate Cancer", Seminars on Urology 127: 45-54 (Exhibit 5);
6. Axelrod, H.R., et al., (1968) "Preclinical results and human immunohistochemical studies with ⁹⁰Y-CYT-356. A new prostate cancer therapeutic agent", Abstract 596. AUA 87th Annual Meeting, May 10-14, 1992. Washington, D.C. (1968) (Exhibit 6);
7. Carter, B.H. and Coffey, D.S. (1990) "The Prostate: An Increasing Medical Problem" The Prostate 16:39-48 (Exhibit 7);
8. Feng, Q., et al. (1991) "Prification and Biochemical Characterization of the 7E11-C5 Prostate Carcinoma-Associated Antigen", Proceedings of the American Association for Cancer Research 32:239 (Exhibit 8);
9. Chang, Chawnshang, et al. (1988) "Structural Analysis of Complementary DNA and Amino Acid Sequences of Human and Rat Androgen Receptors", Proc. Natl Acad. Sci USA 85:7211-7215 (Exhibit 9);
10. Culver, K.W., et al. (1992) "In Vivo Gene Transfer with Retroviral Vector-Producer Cells for Treatment of Experimental Brain Tumors", Science 256:1150-1552 (Exhibit 10);

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11. Decensi, A., et al. (1991) "Phase II Study of the Pure Non-steroidal Antiandrogen Nilutamide in Prostatic Cancer", Eur J Cancer 27:1100-1104 (Exhibit 11);
12. Faber, P.W., et al. (1991) "Characterization of the Human Androgen Transcription Unit", The Journal of Biological Chemistry 266:10743-10749 (Exhibit 12);
13. Fey, Martin F., et al. (1991) "The Polymerase Chain Reaction: A New Tool for the Detection of Minimal Residual Disease in Haematological Malignancies" Eur J Cancer 27:89-94 (Exhibit 13);
14. Henttu, Pirkko and Vihko, Pirkko (1989) "cDNA Coding for the Entire Human Prostate Specific Antigen Shows High Homologies to the Human Tissue Kallikrein Genes" Biochemical and Biophysical Research Communications 160:903-910 (Exhibit 14);
15. Horoszewicz, Julius S., et al. (1987) "Monoclonal Antibodies to a New Antigen Marker in Epithelial Prostatic Cells and Serum of Prostatic Cancer Patients" AntiCancer Research 7:927-936 (Exhibit 15);
16. Huber, Brian E., et al (1991) "Retroviral-mediated Gene Therapy for the Treatment of Hepatocellular Carcinoma: An Innovative Approach for Cancer Therapy" Proc. Natl. Acad. Sci. USA 88:8039-8043 (Exhibit 16);
17. Israeli, Ron S., et al. (1994) "Expression of the

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Prostate Specific Membrane Antigen" Cancer Research
54:1807-1811 (Exhibit 17);

18. Israeli, Ron S., et al. (1994) "Sensitive Nested Reverse Transcription Polymerase Chain Reaction Detection of Circulating Prostatic Tumor Cells: Comparison of Prostate-specific Membrane Antigen and Prostate-specific Antigen-based Assays", Cancer Research 54:6306-6310 (Exhibit 18);
19. Keer, Harold N., et al. (1990) "Elevated Transferrin Receptor Content in Human Prostate Cancer Cell Lines Assessed In Vitro and In Vivo" The Journal of Urology 143:381-385 (Exhibit 19);
20. Lopes, A. Dwight., et al (1993) "Immunohistochemical and Pharmacokinetic Characterization of the Site-specific Immunocnjugate CYT-356 Derived from Antiprostata Monoclonal Antibody" Cancer Research 50: 6423-6429 (Exhibit 20);
21. Lubahn, Dennis B., et al. (1989) "Sequence of the Intron/exon junctions of the Coding Region of the Human Adrogen Receptor Gene and Identification of a Point Mutation in a family with Complete Androgen Insensitivity" Proc. Natl. Acad. Sci. USA 86:9534-9538 (Exhibit 21);
22. Lundwall, Ake and Lilja, Hans., (1987) "Molecular Cloning of Human Prostate Specific Antigen cDNA" FEBS Letters

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214, No. 2:317-322 (Exhibit 22);

23. Mukhopadhyay, Tapas., et al. (1991) "Specific Inhibition of K-ras Expression and Tumorigenicity of Lung Cancer Cells by Antisense RNA¹" Cancer Research 51:1744-1748 (Exhibit 23);
24. Riegman, P.H.J., et al. (1989) "The Prostate-Specific Antigen Gene and the Human Glandular Kallikrein-1 Gene are Tandemly Located on Chromosome 19" FEBS Letters Vol 247:123-126 (Exhibit 24);
25. Sharief, Farida S., et al. "Human Prostatic Acid Phosphatase: cDNA Cloning, Gene Mapping and Protein Sequence Homology With Lysosomal Acid Phosphatase" Biochemical and Biophysical Research Communications 160:79-86 (Exhibit 25);
26. Solin, Timo., (1990) "Gene Expression and Prostate Specificity of Human Prostatic Acid Phosphatase (PAP): Evaluation By RNA Blot Analyses" Biochimica et Biophysica Acta 1048:72-77 (Exhibit 26);
27. Troyer, John K. (1994) "Biochemical Characterization and Mapping of the 7E11-C5.3 Epitope of the Prostate Specific Membrane Antigen (PSMA)", Basic and Clinical Aspects of Prostate Cancer: Abstract C38 (Exhibit 27);
28. Su, S.L., et al. (1994) "Sensitive Detection of Prostatic Hematogenous Micrometastases Using Prostate Specific

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Antigen (PSA) and Prostate Specific Membrane Antigen (PSM) Derived parameters in the Polymerase Chain Reaction" Proceedings of the American Association for Cancer Research 35:271 (Exhibit 28);

29. Vihko, Pirkko., et al (1988) "Molecular Cloning and Sequence Analysis of cDNA Encoding Human Prostatic Acid Phosphatase" FEBS Letters 236:275-281 (Exhibit 29);
30. Vile, Richard G. And Ian R. Hart., (1993) "In Vitro and In Vivo Targeting of Gene Expression to Melanoma Cells" Cancer Research 53:962-967 (Exhibit 30);
31. Israeli, Ron S., et al. (1993) "Molecular Cloning of a Complementary DNA Encoding a Prostate-specific Membrane Antigen" Cancer Research 53:227-230 (Exhibit 31);
32. Waibel, R., et al. (1990) "Therapy of Small Cell Lung Cancer Xenografts in a Nude Mouse model: Evaluation of Radioimmunotherapy and Immunotoxin Therapy" Antibody Immunoconjugates, and Radiopharmaceuticals 3:54 (Exhibit 32);
33. Watt, Kenneth W.K., et al (1986) "Human Prostate-Specific Antigen: Structural and Functional Similarity With Serine Proteases" Proc. Natl. Acad. Sci. USA 83:3166-3170 (Exhibit 33);
34. Wright, Jr., et al., (1990) "Characterization of a New Prostate Carcinoma-Associated Marker" Antibody

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Immunoconjugates, and Radiopharmaceuticals 3:89 (Exhibit 34);

35. Young, Richard A. and Davis, Ronald W., (1983) "Efficient Isolation of Genes by Using Antibody Probes" Proc. Natl. Acad. Sci. USA 80:1194-1198 (Exhibit 35);
36. Israeli, R.S. et al., (1994) "Sensitive Detection of Prostatic Hematogenous Micro-Metastases Using Prostate Specific Antigen (PSA) And Prostate Specific Membrane Antigen (PSM) Derived Primers in the Polymerase Chain Reaction (PCR)" J Urol 151:373A (Exhibit 36);
37. Israeli, R.S. et al., (1994) "Localization of the Prostate Specific Membrane Antigen (PSM) to the Putative Metastasis-Suppressor Region on Human Chromosome 11" J Urol 151:252A (Exhibit 37);
38. Corr, J.G. et al., (1994) "Prostate Specific Membrane Antigen (PSM) Expression in Orthotopically Implanted Human Prostate Cancer Cells in Nude Mice Slows Tumor Growth and Metastatic Potential" J Urol 151:492A (Exhibit 38);
39. Israeli, R.S. et al., (1994) "Localization of the Prostate Specific Membrane Antigen (PSM) to the Putative Metastasis-Suppressor Region on Human Chromosome 11" Proceedings of the American Association for Cancer Research 35:271 (Exhibit 39);

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40. Israeli, R.S. et al., (1993) "Characterization of the Prostate-Specific Membrane Antigen (PSM)" Cancer Research 34:255 (Exhibit 40);
41. Israeli, R.S. et al., (1993) "Molecular Cloning and Characterization of a Prostate-Specific Membrane Antigen" J Urol 149:471A (Exhibit 41);
42. Israeli, R.S. et al., (1992) "Purification and Molecular Cloning of a New Prostate-Specific Antigen" Cancer Research 33:356 (Exhibit 42);

Applicants maintain that none of the foregoing references teach or disclose applicant's invention.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.



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Since no Office Action has been received by applicants, no fee is deemed necessary for filing the Information Disclosure Statement. If any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

Albert Wai Kit Chan

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

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